IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., and TEVA PHARMACEUTICALS USA, INC., Defendants.	C.A. No. 17-3159 (ES)(MAH)
CELGENE CORPORATION, Plaintiff, v. HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., and BRECKENRIDGE PHARMACEUTICAL, INC., Defendants.	C.A. No. 17-3387 (ES)(MAH)

DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
’262 patent	U.S. Patent No. 8,198,262 B2
’262 PH	Prosecution history of the ’262 patent (Murray Declaration Exhibit A)
’427 patent	U.S. Patent No. 8,828,427 B2
’427 PH	Prosecution history of the ’428 patent (Murray Declaration Exhibit D)
’428 patent	U.S. Patent No. 8,735,428 B2
’428 PH	Prosecution history of the ’428 patent (Murray Declaration Exhibit C)
’531 patent	U.S. Patent No. 8,626,531 B1
’720 patent	U.S. Patent No. 6,315,720 B1
’784 patent	U.S. Patent No. 6,755,784 B2
’886 patent	U.S. Patent No. 8,315,886 B2
’939 patent	U.S. Patent No. 8,673,939 B2
’939 PH	Prosecution history of the ’939 patent (Murray Declaration Exhibit B)
’977 patent	U.S. Patent No. 6,561,977 B2
Apotex	Defendants Apotex Inc. and Apotex Corp.
Aurobindo	Defendants Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Limited
Breckenridge	Defendant Breckenridge Pharmaceutical, Inc.
Defendants	Defendants Apotex, Aurobindo, Breckenridge, Hetero, Mylan, and Teva
Hetero	Defendants Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc.
FWD	Final Written Decision (*see* 35 U.S.C. § 318(a))
JCCS	Joint Claim Construction and Prehearing Statement, ECF No. 211

MOT	Method of treatment
MOT patents	’262, ’939, and ’428 patents
Mylan	Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V.
Park Decl.	Declaration of Kinam Park, Ph.D.
PH	Prosecution history
POSA or skilled artisan	Person of Ordinary Skill in the Art
PTAB	Patent Trial and Appeal Board
PTO	United States Patent and Trademark Office
REMS Defendants	Defendants Apotex, Aurobindo, Breckenridge, and Hetero
REMS patents	’720, ’977, ’784, ’886, and ’531 patents
Teva	Defendant Teva Pharmaceuticals USA, Inc.
USP	United States Pharmacopeia

Pursuant to the Court's Scheduling Order (ECF No. 123),[1] Defendants' respectfully submit the instant Opening Claim Construction Brief.

I. INTRODUCTION

Three groups of patents are at issue in this case: (1) the '262, '939, and '428 method of treatment patents ("the MOT patents"); (2) the '427 formulation patent; and (3) '720, '977, '784, '886, and '531 patents, which are directed to a restricted distribution program—also known as a Risk Evaluation and Mitigation Strategy ("REMS")[2] – for certain drugs ("REMS patents"). The Parties respectfully request construction of two terms from the MOT patents (the claim "preambles" and "about 1 mg to about 5 mg per day"), one term from the '427 formulation patent ("total weight of the composition"),[3] and three groups of terms from the REMS patents (the "computer readable," "prescription approval code," and "generator" terms).

With regard to the MOT patents, Defendants maintain that, in accordance with Federal Circuit precedent, the claim preambles are statements of purpose or intended use that do not limit the claims or require any efficacious result. For the "about 1 mg to about 5 mg per day" term of the MOT patents, Defendants seek a construction that the weight requirement applies to each recited form of the active ingredient (*e.g.*, the salt, solvate, stereoisomer, or free base). Relatedly, with regard to the '427 formulation patent, Defendants Teva, Mylan, Breckenridge, and Aurobindo seek a construction for the "total weight of the composition" term such that the recited "total

[1] All "ECF No." references are to the 17-cv-3387 docket unless otherwise specified.

[2] *See* 21 U.S.C. § 355-1, which authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. *In re Suboxone (Buprenorphine HCl and Naloxone) Antitrust Litig.*, MDL No. 2445, 13-MD-2445, 2017 WL 36371, at *2 (E.D. Pa. Jan. 4, 2017).

[3] The JCCS includes additional terms from the '427 patent not argued in this brief (*see* D.I. 211 at 12-15) because Celgene and Defendants Teva, Mylan, Breckenridge, and Aurobindo have since agreed by stipulation that those terms are no longer in dispute and that no construction is required for those terms. Apotex and Hetero have not joined in the stipulation and take no position with respect to any agreements reached therein.

weight" applies to the active ingredient regardless of its form and therefore includes any counter ions and solvent molecules if present.

With regard to the REMS patents, Celgene seeks a construction of the "computer readable" terms as requiring a "centralized" database, while the REMS Defendants do not believe these terms require construction; if they do, based on the intrinsic record and a prior construction by the PTO, they do not require a "centralized" database. For "prescription approval code," Celgene seeks a limiting construction requiring that an "affirmative risk assessment" has been made, presumably to avoid Defendants' prior art, while the REMS Defendants submit that the evidence of record compels a plain and ordinary meaning that does not require any "affirmative risk assessment." Finally, as Celgene chose to describe what generates a "prescription approval code" by functional terms that invoke the strictures of 35 U.S.C. § 112, ¶ 6, but failed to clearly link or associate any structure described in the specification with the recited function, claims 1-20 of the '531 patent are indefinite.

II. LEGAL STANDARDS

"[T]he words of a claim are generally given their ordinary and customary meaning . . . to a person of ordinary skill in the art." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal quotations omitted). The claims "must be read in view of the specification, of which they are a part," and the Court "should also consider the patent's prosecution history." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Absent the limited circumstances of either lexicography or disavowal, that ordinary meaning controls. *GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). The Court is permitted to rely on extrinsic evidence, including expert testimony and learned treatises, to determine a claim term's plain meaning, although extrinsic evidence is "less significant than the intrinsic record in determining

'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (citation omitted).

III. LEVEL OF ORDINARY SKILL IN THE ART

The person of ordinary skill in the art ("POSA" or "skilled artisan") to whom the '427 patent is directed is a person involved in the research and development of pharmaceutical formulations and dosage forms, and would have a Ph.D. in a field related to "pharmaceutical sciences" (such as pharmaceutics, physical chemistry, medicinal chemistry, chemistry, chemical engineering, or biochemistry) and at least one year of experience in pharmaceutical formulation. The POSA to whom the MOT patents are directed would be a clinical or medical oncologist with several years of experience in cancer research, treatment, and/or clinical trials and, who could work with a team of individuals, including a person with an advanced degree in pharmaceutical sciences. The POSA with respect to the REMS patents includes health care providers, pharmacists and other persons having experience restricting the distribution of drugs with safety concerns.

The qualifications for the POSA can be met by one person or a team of individuals, and the skilled artisan could have a lower level of formal education if that person has a higher degree of experience. Defendants' expert Dr. Kinam Park meets and exceeds these criteria with respect to the '427 formulation patent and with respect to the dosage and chemistry elements of the asserted MOT patent claims. Park Decl. ¶¶ 6-19.

IV. ARGUMENT

A. The MOT Patents ('262, '939, and '428 Patents)

The asserted MOT patent claims are generally directed to methods of treating multiple myeloma—a cancer of the blood plasma cells—by cyclic administration of 1-5 mg of pomalidomide, an anti-cancer drug. ECF No. 1, Compl. Ex. A, '262 patent 24:4-9, 38:17-40:22; *id*. at Ex. B, '939 patent 38:65-40:57; *id*. at Ex. C, '428 patent 39:2-40:47.

1. The Preambles

Claim Term	Celgene's Proposal	Defendants' Proposal[4]
"A method of treating multiple myeloma"[5] '262 patent claims 1-2, 4-16, 18-27, 29; '939 patent claims 1-14, 16-35; '428 patent claims 1-27	"A method for treating multiple myeloma" is limiting, such that the term requires efficacy in treating multiple myeloma	"A method of treating multiple myeloma" is not limiting

a. The Preambles Are Non-Limiting

The preamble is the language of a patent claim that precedes the transitional phrase; in the case of the asserted claims of the MOT patents, the language "[a] method of treating multiple myeloma" before the transitional phrase "which comprises." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 949 (Fed. Cir. 2006). "Generally, [as the Federal Circuit] ha[s] said, the preamble does not limit the claims." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (internal quotes omitted) ("*AMS*"). "A preamble is not regarded as limiting, . . . , when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id*. at 1358-59 (internal quotations omitted).

Going against the general presumption, Celgene requests that this Court treat the preambles of the asserted MOT patent claims as limitations "requir[ing] efficacy in treating multiple myeloma." ECF No. 211, JCCS Ex. A at 1. Celgene seeks such a limiting construction so that it

[4] To conserve court and party resources, Apotex and Hetero hereby withdraw their proposed alternative construction for the preambles. *See* ECF No. 211, JCCS Ex. A at 5-7.

[5] In the JCCS, the Parties inadvertently mis-described the asserted MOT patent claim preamble language as "[a] method ***for*** treating multiple myeloma." *Compare* ECF No. 211, JCCS Ex. A at 1, *with* ECF No. 1, Compl. Ex. A, '262 patent 38:17-40:22; *id*. at Ex. B, '939 patent 38:65-40:57; *id*. at Ex. C, '428 patent 39:2-40:47. Defendants hereby correctly identify the asserted MOT patent claim preamble language as "[a] method of treating multiple myeloma."

may argue during the merits phase of this case, incorrectly, that Defendants' prior art does not anticipate or render obvious the asserted MOT patent claims because the prior art allegedly did not disclose that administration of pomalidomide would be efficacious in treating multiple myeloma.[6] Celgene's attempt to secure a limiting construction of the preambles should be rejected, because (1) the plain language of the claims shows the preambles are nothing more than statements of purpose or intended use that do not recite essential structure or steps and that precede structurally complete methods; (2) the common specification[7] of the MOT patents includes no clinical data establishing that the claimed methods are efficacious in treating multiple myeloma; and (3) Celgene did not clearly rely on the preambles to establish patentability for its claims.

i. The Preamble Language Supports Defendants' Position

Each of the asserted MOT patent claims begins with the preamble "[a] method of treating multiple myeloma," followed by the transitional phrase "which comprises," and then includes a body that sets out the specific claimed method, with all of the steps required to be carried out for the claimed method. ECF No. 1, Compl. Ex. A, '262 patent 38:17-40:22; *id*. at Ex. B, '939 patent 38:65-40:57; *id*. at Ex. C, '428 patent 39:2-40:47. The body and claim elements (or steps) of each asserted MOT claim do not rely on the preamble, whether for definition or antecedent basis. *Id*. The "method [is] performed in the same way regardless [of] whether or not the patient experiences" an efficacious result. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Ltd.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001) ("*BMS*"). While the term "multiple myeloma" is used in both the body of the claims and in the preamble, the reference in the body—used to specify the patient to whom pomalidomide is administered according to the claimed method—does not in any way rely

[6] Defendants believe that the prior art did in fact disclose that pomalidomide would be effective in treating multiple myeloma.
[7] The MOT patents share a common specification. ECF No. 211, JCCS Ex A at 2 n.5.

on the reference to multiple myeloma in the preamble. *Id*. "[T]he mere fact that a . . . term in the preamble is part of the claim does not mean that the preamble's statement of purpose or other description is also part of the claim." *Marrin v. Griffin*, 599 F.3d 1290, 1295 (Fed. Cir. 2010).

"If the preamble is reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim (and was not clearly added to overcome a [prior art] rejection), [the Federal Circuit] do[es] not construe it to be a separate limitation." *AMS*, 618 F.3d at 1359. As explained below, the preambles of the asserted MOT patent claims were not added in response to prior art rejections by the Patent Office, or in any way relied upon by Celgene to overcome prior art rejections. "A method of treating multiple myeloma" is merely a statement of intended use, and the reference to "multiple myeloma" in the preamble is duplicative of the reference in the body of the claim. "Removal of the duplicative preamble language would neither alter the scope of the claims nor introduce ambiguity as to their coverage." *Id*. at 1360.

AMS is on point. There, the method claim preamble language recited "[a] method of photoselective vaporization of tissue," which was followed by the transitional phrase "comprising," which led into the body of the claims that recited a complete method, including the step of "delivering laser radiation to the tissue." *Id.* at 1356. Finding that the preamble merely gave a descriptive name to the set of limitations in the body of the claim, which contained "all of the steps necessary to practice the invention," the Federal Circuit found the preamble language non-limiting. *Id*. at 1359-60. In doing so, the Federal Circuit rejected the argument that the "tissue" reference in the preamble provided necessary antecedent basis to the term "the tissue" in the body of the claims, finding that the preamble reference "does not specify a particular type or locations of tissue being treated." *Id*. at 1359. Similarly, here, the "multiple myeloma" recitation in the preamble provides no meaningful antecedent basis to the recitation of "multiple myeloma"

in the body of the claims, which specifies the patient to whom medication is being administered. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1990) (If the preamble offers no distinct definition of any of the claimed invention's limitations, then it cannot be said to constitute or explain a claim limitation.); *Marrin*, 599 F.3d at 1295 (identifying cases in which preamble was found non-limiting where term in preamble was also recited in the body); *ICN Pharm., Inc. v. Geneva Pharm. Tech. Corp.*, 272 F. Supp. 2d 1028, 1044-45 (C.D. Cal. 2003).

This Court has previously ruled that preamble language in the context of prostate cancer method of treatment claims similar to the MOT patent preambles in the instant case is not limiting, and does not require efficacy. In *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC,* No. 14-7869-MAS-LHG (consolidated), 2016 WL 5898627 (D.N.J. Oct. 7, 2016), the preambles of two independent claims of a method patent recited "[a] method for treating a patient with prostate cancer that has progressed during or after treatment with docetaxel" (claim 1) and a "method of increasing the survival of a patient with a castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel" (claim 27). *Sanofi-Aventis*, 2016 WL 5898627, at *4. The parties agreed that the portions of the claim 1 and 27 preambles ***after*** "[a] method for treating" and "[a] method of increasing the survival" were limiting. However, the brand patent owner Sanofi also argued that the "[a] method for treating" and "[a] method of increasing the survival" portions of the preambles were also limitations requiring efficacy. *Id*. at *5-6. This Court agreed with the generic drug defendants that the contested portions of the preambles were merely statements of intended use that did not "recite an essential structure or step," and that the steps of the claimed methods were performed the same way and did not require an efficacious result. *Id*. at *4-5. The preamble language and overall claim structure of the instant asserted MOT patent claims are very similar to the method claim

preambles and claim structures at issue in *Sanofi-Aventis*, and warrant a similar treatment.

ii. The Specification Supports Defendants' Position

Celgene seeks limiting constructions for the preambles of the asserted MOT patent claims so that it may argue during the merits phase of this case that its MOT patents are not invalid because the prior art relied on by Defendants for their anticipation and obviousness defenses does not disclose that pomalidomide would be effective in treating multiple myeloma. But Celgene intends to demand more from the prior art than the evidence it provided in support of its own claims, which is contrary to law. *See Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014). Specifically, there is no evidence in the common specification that pomalidomide is efficacious in treating patients with multiple myeloma. The common specification contains absolutely no clinical efficacy data for pomalidomide. Thus, the preambles should not be construed to require that the claimed methods be efficacious when Celgene never supported its claims with efficacy data in patients for pomalidomide.[8]

Beyond the lack of efficacy data for pomalidomide, the common specification includes additional information supportive of Defendants' position. Specifically, the common specification states that "[a]s used herein, unless otherwise specified, the term 'treating' refers to the administration of a compound of the invention or other additional active agent after the onset of symptoms of the particular disease or disorder." ECF No. 1, Compl. Ex. A, '262 patent 16:11-15.

[8] Even if the common specification contained such clinical efficacy data, that would not be dispositive of whether the preambles should be construed as limitations requiring efficacy. The method patent construed in *Sanofi-Aventis* itself contained Phase III human clinical trial data establishing that cabazitaxel and prednisone were effective for treating docetaxel-resistant prostate cancer. *Sanofi-Aventis*, 2016 WL 5898627, at *4-6; *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, No. 14-cv-7869-MAS-LHG, ECF No. 58-8, Decl. of Roger J. Kiley Ex. 3, U.S. Patent No. 8,927,592 B2 at 10:28-17:34 (Example 1) (D.N.J. Dec. 3, 2015); *id*. at ECF No. 328, Redacted Opinion at 61-62, 75-76 (April 25, 2018). Nevertheless, this Court refused to construe the preambles of the corresponding method claims as limitations requiring efficacy.

This language—definitional in nature—does not require that "treating" be effective, and suggests that "[a] method of treating" requires nothing more than the administration of the medications recited in the method steps of the asserted MOT patent claims.

iii. There Was No "Clear Reliance" on the Preambles During Prosecution.

"Clear reliance on a preamble during prosecution can distinguish a claimed invention from the prior art and render the preamble a claim limitation." *Marrin*, 599 F.3d at 1294. "Clear reliance" generally requires that the preamble be "added to overcome a prior art rejection." *AMS*, 618 F.3d at 1359 (internal brackets omitted); *Sanofi-Aventis*, 2016 WL 5898627, at *4 ("clear[] and unmistakeabl[e] reli[ance]" during prosecution required to turn an otherwise non-limiting preamble into a limitation (internal quotations omitted)). The applicants for the MOT patents never relied on the preambles to distinguish the prior art. First, for each of the three MOT patents, the preambles were part of the original application claims submitted to the Patent Office for examination, and, thus, were not added to overcome prior art rejections.[9] *AMS*, 618 F.3d at 1359 (no clear reliance where there was no suggestion preamble language was added to overcome prior art rejections).

Second, while the MOT patent applicants made certain arguments to the Patent Office regarding efficacy in response to prior art rejections, those arguments bore no relation to the preamble language of the asserted MOT patent claims. As a first example, in discussing the prior

[9] *See* Murray Decl. Ex. A, '262 PH, Aug. 19, 2008 Original Appl. at 52-57 (CELPOM00000147-150); *id*. at Aug. 19, 2008 Prelim. Amendment at 1-7 (CELPOM00000157-167); Murray Decl. Ex. B, '939 PH, Mar. 1, 2013 Original Appl. At 52-57 (CELPOM00000903-08); *id*. at Mar. 1, 2013 Prelim. Amendment at 1-8 (CELPOM00000946-953); Murray Decl. Ex. C, '428 PH, Mar. 1, 2013 Original Appl. at 52-57 (CELPOM00001204-09); *id*. at Mar. 1, 2013 Prelim. Amendment at 1-7 (CELPOM00001258-264); *see also*, 37 C.F.R. § 1.115(a)(1) ("A preliminary amendment that is present on the filing date of an application is part of the original disclosure of the application."); *Harari v. Hollmer*, 602 F.3d 1348, 1351-53 (Fed. Cir. 2010).

art asserted by the Patent Office in connection with an obviousness rejection, the applicants argued that "there is no suggestion in the cited art that pomalidomide is effective to treat multiple myeloma."[10] This statement, however, is a characterization of the prior art, and was part of the applicants' argument about whether there would have been a reasonable expectation of success in using pomalidomide to treat multiple myeloma. The statement did not in any way "distinguish the patented invention from the prior art based on the [preamble language]," and therefore does not transform the preamble into a limitation. *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1238 (Fed. Cir. 2017). As was the case in *Sanofi-Aventis*, the MOT patent applicants' arguments regarding whether the prior art provided a reasonable expectation of success in using pomalidomide to treat multiple myeloma does not amount to a "clear[] disclaime[r] or disavow[al] [of] the claimed invention when it does not produce . . . efficacious results." *Sanofi-Aventis*, 2016 WL 5898627, at *6; *see also Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) ("Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution.").

As a second example, in response to the Patent Office's obviousness rejection, the applicants argued that certain literature submitted to the Office was evidence of "unexpected results" showing that "the pomalidomide/dexamethasone regimen is significantly active in refractory myeloma."[11] Again, these arguments were in no way tied to the preambles. At least one sister district in this Circuit has recognized that there is a difference between clear reliance on a preamble to overcome a prior art rejection and "touting the unexpected results of all claimed

[10] *See, e.g.*, Murray Decl. Ex. A, '262 PH, Dec. 20, 2011 Amendment and Resp. at 6 (CELPOM00000303).
[11] *See, e.g.*, Murray Decl. Ex. A, '262 PH, Dec. 20, 2011 Amendment and Resp. at 10 (CELPOM00000307)

methods as a secondary consideration of nonobviousness during prosecution," the latter being insufficient to convert a claim preamble into a limitation. *Takeda Pharm. Co. v. Actavis Labs FL, Inc.*, No. 15-451-RGA, 2016 WL 3193188, at *8 n.8 (D. Del. June 6, 2016) ("The patentee's broad, consistent references to the entire '195 patent's unexpected results during prosecution do not provide adequate grounds to conclude that it relied upon the preamble of claim 11 to overcome the examiner's specific rejection of claim 11.").

Ultimately, the application claims of the '262 patent were allowed after amendments to require cyclical administration of pomalidomide and dexamethasone, and the application claims of the '939 and '428 patents were allowed after amendments to specify that the multiple myeloma treated is relapsed or refractory (or both), and submission of a supporting declaration alleging that treatment of relapsed or refractory multiple myeloma with pomalidomide was an unexpected result.[12] None of these amendments involved the preambles or a disavowal/disclaimer of the invention when efficacious treatment is not achieved. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810 (Fed. Cir. 2002) (although the applicants mentioned the preamble during prosecution, claim amendments to distinguish the prior art were only made to the claim body and were thus insufficient to convert the preambles into limitations).

Thus, there was never any reliance on the preambles of the asserted MOT patent claims during prosecution to overcome the prior art. Because the preambles are nothing more than statements of intended use, this Court should hold that they are not limitations.

[12] Murray Decl. Ex. A, '262 PH, Mar. 15, 2012 Resp. and Statement of Interview Summary at 1-6 (CELPOM00000337-342); Murray Decl. Ex. B, '939 PH, Oct. 8, 2013 Resp. at 1-7 (CELPOM00001068-074); *id*. at Oct. 3, 2013 Decl. of A. Thakurta at 1-3 (CELPOM00001082-84); Murray Decl. Ex. C, '428 PH, Oct. 9, 2013 Resp. at 1-6 (CELPOM00001370-75); *id*. at Oct. 3, 2013 Decl. of A. Thakurta at 1-3 (CELPOM00001383-385).

2. "about 1 mg to about 5 mg per day …."

Claim Term	Celgene's Proposal	Defendants' Proposal
"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically acceptable salt, solvate, or stereoisomer thereof" '262 patent claim 1-2, 4-16, 18-27, 29; '939 patent claim 1-14, 16-25; '428 patent claim 1-21	"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically acceptable salt, solvate, or stereoisomer containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"	"about 1 mg to 5 mg . . . of a compound having the formula [ ] or about 1 mg to 5 mg of a pharmaceutically acceptable salt or solvate of [ ] or about 1 mg to 5 mg of any single stereoisomer of [ ]"
"about 1 mg to about 5 mg of a compound having the formula [of pomalidomide] or a solvate thereof" '939 patent claim 26-35; '428 patent claim 22-27	"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a solvate containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"	"about 1 mg to 5 mg . . . of a compound having the formula [ ] or about 1 mg to 5 mg of a solvate of [ ]"

The MOT patents broadly claim the type of active ingredient that can be used in the claimed methods of treatment. Defendants' proposed constructions merely follow the language of the claims by stating that the "about 1 mg to about 5 mg" weight limitation applies to the alternative forms of the administered drug (*i.e.*, pomalidomide compound, a pharmaceutically acceptable salt or solvate of pomalidomide, or any single stereoisomer of pomalidomide). The Court should adopt Defendants' proposed construction of these terms because they are supported by the record evidence, while Celgene's proposed construction contradicts the clear language of the claims.

The MOT patents consistently describe the invention as treatment with an active ingredient that may take several different forms, either as the pomalidomide compound on its own (*i.e.*, in a so-called "free base" form) (Park Decl. ¶¶ 36, 40) **or** as a pharmaceutically acceptable salt, solvate, stereoisomer, or other form thereof. ECF No. 1, Compl. Ex. A, '262 patent at 4:13-18; 4:53-60,

5:14-28, 7:20-40, 8:45-63, 18:5-11, 23:20-25, 24:62- 25:3, 30:44-47. The skilled artisan reviewing the pertinent language of the specification, which is similar to that of the claims, would have understood the patentee to have used the word "or" to identify different, alternative forms for the active ingredient. *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1199–200 (Fed. Cir. 2013) ("The disjunctive 'or' plainly designates that a series describes alternatives." (citing *Kustom Signals, Inc. v. Applies Concepts, Inc.*, 264 F.3d 1326, 1331 (Fed. Cir. 2001) (explaining that "or" designates alternatives))). As such, the POSA would also have understood the claimed weight requirement (*i.e.*, "about 1 mg to about 5 mg") to apply to each of these alternatives. Park Decl. ¶¶ 50-53, 56–61.

This distinction is important because, for example, 1 mg of these different forms will contain different amounts of the basic pomalidomide. For instance, when the form of pomalidomide is as a "pharmaceutically acceptable salt," the 1 mg weight includes not only the weight of the pomalidomide moiety but also the weight of the proton and counterion of the "non-toxic acid ... addition salts." Thus, the pomalidomide moiety is less than 1 mg. By contrast, 1 mg of the free base form of pomalidomide would have 1 mg of the pomalidomide moiety. ECF No. 1, Compl. Ex. A, '262 Patent at 9:57–10:12; Park Decl. ¶¶ 40–43. A POSA would have understood that the "addition salts" described by the specification comprise additional chemical elements, such as chlorine and hydrogen, each of which have their own molecular weight. Park Decl. at ¶¶ 42–43. Similarly, for the recited "solvates," a POSA would have understood that the additional bound solvent would have its own molecular weight to account for the additional molecules present (*e.g.*, H_2O, would be present if the solvent was water). *Id.* ¶¶ 44–45. Thus, the claims are directed to treatment with different doses of pomalidomide depending on whether the claimed weight requirement applies to the active ingredient as a whole (which can be a salt or solvate)—

as Defendants propose—or to only the pomalidomide portion—as Celgene appears to propose.

The intrinsic and extrinsic evidence confirm Defendants' proposed construction. For example, the specification states:

> [T]he amounts and specific types of active ingredients in a dosage form may differ depending on factors such as, but not limited to, the route by which it is to be administered to patients. However, typical dosage forms of the invention comprise an ***immunomodulatory compound*** of the invention or ***a pharmaceutically acceptable salt, solvate***, hydrate, ***stereoisomer***, clathrate, or prodrug thereof ***in an amount of from about 0.10 to about 150 mg***. Typical dosage forms comprise an ***immunomodulatory compound*** of the invention or a ***pharmaceutically acceptable salt, solvate***, hydrate, ***stereoisomer***, clathrate, or prodrug thereof ***in an amount of about 0.1, 1, 2, 5, 7.5, 10, 12.5, 15, 17.5, 20, 25, 50, 100, 150 or 200 mg***.

'262 Patent at 26:48–56 (emphasis added). The POSA reading this passage would have understood that the amount of any of the listed forms of the active ingredient could be an amount between about 0.10 to about 150 mg, or any of the specified amounts between 0.1 and 200 mg. *See* Park Decl. ¶¶ 57–58. In particular, it is the ***pharmaceutically acceptable salt, solvate, or stereoisomer*** that is described here as being "in an amount of about …"—when the active ingredient is not the pomalidomide compound alone. A POSA, reading the claims in light of the specification, would have understood that the term "about 1 mg to 5 mg" applies to the weight of the entirety of the molecule present. *Id.*

As Dr. Park explains in his declaration, Defendants' construction is also consistent with the standard practice in the field when active ingredients are administered as a salt or solvate. Park Decl. ¶¶ 59–61. For example, *Pharmaceutical Calculations* (H. Ansel, 13th. Ed. 2010 & 11th Ed. 2001) specifies that pharmacists should calculate the amount of "active drug moiety" (*i.e.*, the molecule responsible for the physiological effect, here pomalidomide itself) in a given composition by "taking into account the molecular composition of the substance." Park Decl. Ex. 7 (2010 Ansel) at 328; *id.* Ex. 8 (2001 Ansel) at 256. Similarly, the *United States Pharmacopeia* provides that "[c]alculations must account for the active ingredient, or active moiety, and water content of

drug substances, which includes that in the chemical formulas of hydrates," or, in the case of a salt, "calculated on the basis of the required quantity of the pharmacological moiety." Park Decl. Ex. 9 (2008 USP) at 627; *see also id.* Ex. 10 (2000 USP). Such guidance is consistent with a POSA's understanding that the weight of an active ingredient must account for the specific form of the drug, and include any counter ions or solvent molecules. Park Decl. ¶¶ 59-61. For this additional reason, the POSA reading the MOT patents would have understood that the claims specify the absolute weight (*i.e.*, "about 1 mg to 5 mg") of whichever pomalidomide form present.

With respect to the first form of the administered drug recited in the claims (*i.e.*, a compound having the formula [of pomalidomide]), the POSA would have understood this to refer to a mixture of stereoisomers, since these claims depict a chemical structure without indicating its stereochemistry. ECF No. 1, Compl. Ex. A, '262 Patent at 11:40-46 ("[I]f the stereochemistry of a structure or a portion of a structure is not indicated with, for example, bold or dashed lines, the structure is to be interpreted as encompassing all stereoisomers of it."); Park Decl. ¶¶ 36-39, 54–55. This understanding would have informed the POSA as to the intended meaning of the stereoisomer portion of the claim (*i.e.*, "about 1 mg to about 5 mg of … a … stereoisomer thereof"). Although the article "a" can be construed as "one or more," such a construction would be redundant here, as the claim already includes combinations of stereoisomers. *See Harari v. Lee*, 656 F.3d 1331, 1341 (Fed. Cir. 2011). Thus, the POSA would have understood this portion of the claim to refer to "about 1 mg to 5 mg of ***any single*** stereoisomer." *See Amgen Inc. v. Hospira, Inc.*, Civil Action No. 15–839–RGA, 2016 WL 7013483, at *2 (D. Del. 2016) (construing "an isolated … isoform" as limited to a mixture of a ***single isoform*** because a construction allowing "for mixtures ***of at least one isoform***" "would render the word 'isolated' superfluous" (emphasis added)); *see also Azko Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1340 (Fed. Cir.

2016) (citing *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."); *Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004) ("[I]nterpretations that render some portion of the claim language superfluous are disfavored.")). This distinction is non-trivial because the functions of a particular compound (*e.g.*, its stability or therapeutic effectiveness) can depend on the particular stereoisomer. Park Decl. ¶¶ 54-55.

Accordingly, the Court should adopt Defendants' proposed constructions of these terms, which are consistent with the evidence and the clear meaning of the claims.

B. The '427 Formulation Patent[13]

1. "Total Weight Of The Composition"

Claim Term	Celgene's Proposal	Defendants' Proposal[14]
"total weight of the composition" '427 patent claims 3-10	No construction required.	"total weight of the composition including the weights of counter ions and solvent molecules, if present"

Claims 3-10 of the '427 patent are directed to oral dosage forms in the form of a capsule, and each claim recites specific amounts of "100% pure pomalidomide," "pregelatinized starch," and "sodium stearyl fumarate," as well as a specific "total weight of the composition." Although each claimed capsule requires "spray dried mannitol," the amount of mannitol required is whatever brings the formulation up to the "total weight" after all other ingredients are accounted for (*i.e.*,

[13] Teva, Breckenridge, and the Mylan Defendants have been sued in this Court (Case Nos. 2:18-cv-14366, 2:18-cv-13715, and 2:18-cv-16035) by Celgene pursuant to the same ANDA filings that are at issue in these coordinated actions asserting a patent having the same specification as the '427 Patent. These defendants believe judicial resources will be conserved if that case is coordinated with the present case.

[14] Defendants Teva, the Mylan Defendants, Breckenridge, and Aurobindo propose this construction. *See* D.I. 211, JCCS at 15–17.

"spray dried mannitol at an amount that brings the total weight of the composition to 125 mg").

Similar to the claims of the MOT patents discussed above, the claims of the '427 patent include multiple, alternative forms for the active ingredient pomalidomide (*i.e.*, "pomalidomide, or a pharmaceutically acceptable salt or solvate thereof"). Unlike the claims of the MOT patents, however, the '427 patent's claims explicitly identify the amount of pure pomalidomide to be found in the claimed capsule (*i.e.*, "[x] mg of 100% pure pomalidomide"). ECF No. 1, Compl. Ex. D, '427 patent at 2:39-3:3. Thus, whatever the form of the pomalidomide in the capsule (*e.g.*, whether a salt, solvate, or free base), that weight is adjusted so as to provide the equivalent of [x] mg of 100% pure pomalidomide not including the salt or solvate weight.

As explained above in Section IV.A.2, the POSA would have understood that, when a compound is in the form of a "pharmaceutically acceptable salt or solvate," the presence of counter ions and solvent molecules increases the molecular weight over that of the compound alone. Park Decl. ¶¶ 40–45*; see also*, ECF No. 1, Compl. Ex. D, '427 patent 2:39-64 (defining "pharmaceutically acceptable salt" as including "salts of acidic or basic moieties of thalidomide"); *id*. at 2:65-3:3 (defining "solvate" as including an "amount of solvent" that is bound to the compound). This increased weight when the active ingredient is in the form of a "pharmaceutically acceptable salt or solvate" is accounted for in the claimed capsules by reducing the amount of mannitol necessary to get to the claimed "total weight." Park Decl. ¶¶ 63-67. Likewise, these "comprising" claims are open-ended and can include additional excipients other than the recited starch, mannitol, and fumarate. In other words, the mannitol amount would decrease when counter ions and solvent molecules are present, or if additional unrecited excipients are present, so that the capsule may still contain 1 mg of 100% pure pomalidomide and a total weight of 125 mg. *Id*. Thus, the "total weight of the composition" should be defined as "including the weights of counter

ions and solvent molecules" when the pomalidomide compound is in the form of a salt or solvate.

This understanding of the claims is supported by the intrinsic record. The specification of the '427 patent explicitly describes this situation where the weight of the active ingredient form is greater than the weight of the pomalidomide itself:

> In some embodiments, because it is typical to obtain pomalidomide, or a pharmaceutically acceptable stereoisomer, prodrug, salt, solvate, or clathrate thereof, at a purity of less than 100%, the formulations and dosage forms provided herein may be defined as compositions, formulations, or dosage forms that comprise pomalidomide, or a pharmaceutically acceptable stereoisomer, prodrug, salt, solvate, or clathrate thereof, ***at an amount that provides the potency of a specified amount of 100% pure pomalidomide***.

ECF No. 1, Compl. Ex. D, '427 patent at 7:26-34 (emphasis added); *see also, id.* at Examples 1-6 (indicating weight for pomalidomide "corresponds to the amount that provides the potency of [x] mg of pomalidomide"). This passage explains that, even when the obtained form of pomalidomide is a salt, solvate, or otherwise less than 100% pure, the formulation will include more of the pomalidomide in order to reach the equivalent of the specified amount of 100% pure pomalidomide. *See also* Park Decl. ¶¶ 64-66.

Although the language in this passage is not exactly the same as in the claims, this passage was relied on by the Applicants during prosecution to explain the meaning of the pomalidomide limitation. Park Decl. ¶¶ 31–32, 64–65. In fact, the claims as originally submitted to the Patent Office each required a particular "potency" of pomalidomide. *Id.* ¶¶ 30–31 (showing original claims to recite "[x] mg ***potency*** of pomalidomide"). The Examiner rejected the claims as indefinite because of this language and the Applicants repeatedly argued that the limitation was clear because it referred to the amount of 100% pure pomalidomide. *Id.* ¶¶ 31–34, 64–65. For example, the Applicants argued:

> [A]s those skilled in the art would clearly understand from this language, the claim contemplates that pomalidomide, or a pharmaceutically acceptable salt or solvate, would be contained in the claimed formulation in an amount that would provide the

> same potency as X mg of pomalidomide free base. In other words, the "mg" unit recited by the claims does not refer to the actual potency of the active ingredient, but instead refers to the amount of pomalidomide free base that would provide the required potency.

Murray Decl. Ex. D. '427 PH, Feb. 12, 2013 Amendment and Resp. at 7-8 (CELPOM00001823–24). Thus, the POSA would have understood from the arguments made in the prosecution history, as well as from the subsequent amendments to the claims to recite "100% pure" instead of "potency," that the weight of the pomalidomide API would be adjusted in order to ensure that the capsule included the equivalent of the specified amount of 100% pure pomalidomide. Park Decl. ¶¶ 30-35, 63-67. If a salt or solvate was used, the "total weight of the composition" would then account for the additional counter ions and solvent molecules. *Id.*

Defendants' construction is also consistent with the extrinsic evidence, which is also discussed above in Section IV.A.2 and provides that the calculation of weight must account for the specific form of the active ingredient. *See also* Park Decl. Ex. 7 (2010 Ansel) at 328; *id.* Ex. 8 (2001 Ansel) at 256; *id.* Ex. 9 (2008 USP) at 627; *id.* Ex. 10 (2000 USP). With respect to the '427 patent's claims, the "total weight of the composition" must account for the specific form of pomalidomide present in the capsule, and thus, would include counter ions (in the case of a pomalidomide salt) and solvent molecules (in the case of a pomalidomide solvent). *Id.* ¶¶ 63, 67-70; *see also* Section IV.A.2.

Defendants' proposed construction provides the plain and ordinary meaning of this term, consistent with the intrinsic and extrinsic evidence. As Celgene provides no alterative construction, the Court should adopt Defendants' proposal. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008)

C. The REMS Patents[15]

1. The "Computer Readable" Terms

I. Claim Term	Celgene's Proposal	Defendants' Proposal
"computer readable storage medium" '720 patent claims 1-21, 23-32; '977 patent claims 1-23, 25-34; '784 patent claims 1-23, 25-34; '886 patent claims 1-7 * * * "computer readable medium" '531 patent claims 1-40	"a centralized database that includes all registration information regarding the claimed prescribers, pharmacies, and patients"	No construction necessary, but if construed, should be construed to have its plain and ordinary meaning, which is "computer readable storage medium, which may or may not be centralized" or "computer readable medium, which may or may not be centralized"

The asserted claims of the '720, '977, '784 and '886 patents require a "computer readable storage medium," while the asserted claims of the '531 patent require a "computer readable medium." The REMS Defendants contend these terms need not be construed, but that if they are construed, they should be construed as requiring a medium that may or not be centralized. Celgene contends that the disputed terms should be construed to require "a centralized database that includes all registration information regarding the claimed prescribers, pharmacies and patients." The evidence demonstrates that the REMS Defendants are correct, including an IPR proceeding involving Celgene's closely-related U.S. Patent No. 6,045,501 ("the '501 patent"), where the PTAB concluded that the term "computer readable storage medium" in the claims of the '501 patent did not require construction, but that if it was construed, it should ***not*** be construed as requiring a "centralized" database.

[15] These patents are not asserted against Teva or the Mylan Defendants, and those defendants take no position on any of the proposed terms for construction.

a. These Terms Do Not Require Construction

These terms do not need construction. The common specification of the REMS patents indicates that the term "computer readable storage medium" is a common term familiar to those of ordinary skill in the art (ECF No. 26-1, Hetero Answer Ex. A, '720 patent 5:11-16), and does not define that term or indicate that any deviation from its plain and ordinary meaning is appropriate. And, as noted above, the PTAB found that the term "computer readable storage medium" from the closely-related '501 patent did not need construction. As such, the REMS Defendants submit that no construction is necessary. *See also Audatex N. Am., v. Mitchell Int'l, Inc.*, No. 13-cv-1523-BEN (BLM), 2014 WL 5800959, *5-6 (S.D. Cal. Nov. 6, 2014) (holding that no construction was necessary for "computer readable storage medium" as found in the claims of another patent).

b. If Construed, They Should Be Construed as Requiring a Medium That May or May Not Be Centralized

The evidence demonstrates that the terms "computer readable storage medium" and "computer readable medium" do not require a "centralized database" (*i.e.*, a single database) that "includes all registration information regarding the claimed prescribers, pharmacies, and patients." For one thing, the common specification of the REMS patents indicates that prescriber, patient, and pharmacy information ***may*** all be stored in the same computer readable storage medium, ***or*** that such information may be stored in separate computer readable storage media. Specifically, after indicating that prescriber registration information may be stored in a computer readable storage medium (ECF No. 26-1, Hetero Answer Ex. A, '720 patent 5:5-16), the specification indicates that pharmacy registration information is preferably also entered into a "computer readable storage medium," and that that computer readable storage medium "***may be the same as, or different from*** the computer readable storage medium in which the prescribers are registered"

(*id*. at 5:17-23 (emphasis added)). The specification then indicates that patient registration information is preferably stored in a computer readable storage medium, and that computer readable storage medium "***may be the same as, or different from*** the computer readable storage medium in which the prescriber and/or pharmacy are registered." *Id*. at 5:60-67 (emphasis added). The specification thus explicitly uses the term "computer readable storage medium" to refer to a medium in which (1) only prescriber registration is stored, (2) only pharmacy registration information is stored, or (3) only patient information is stored. This is inconsistent with Celgene's proposed construction, where "computer readable storage medium" means a single, centralized database in which ***all*** prescriber, pharmacy and patient registration information is stored.

Like the specification of the REMS patents, the specification of the '501 patent explicitly contemplates an arrangement in which prescriber, pharmacy and patient registration information are stored in three separate computer readable storage media. Indeed, the specification of the '501 patent uses almost identical language to describe this arrangement. Murray Decl. Ex. E, '501 patent 4:50-57 (regarding pharmacies); *id*. at 5:25-33 (regarding patients). In concluding that the term "computer readable storage medium" did not require a single, centralized database, the PTAB relied on this language in the specification of the '501 patent, stating that "[Celgene's] position – that the storage medium of claim 1 must be 'centralized' to include, in one database, all registration information – is not supported by the disclosure of the '501 patent specification." Murray Decl. Ex. F, FWD in IPR2015-01092, at 10.

Other intrinsic evidence showing that Celgene's proposed construction is wrong involves the use of the term "computer readable storage medium" in certain dependent claims of the REMS patents. For example, claim 1 of the '784 patent requires entering certain patient information in a "computer readable storage medium." ECF No. 26-3, Hetero Answer Ex. C, '784 patent at claims.

Claim 2 is dependent on claim 1 and ***adds*** the requirement that the physician who prescribed the drug (*i.e.*, the prescriber) be registered in the "computer readable storage medium" of claim 1. *Id.* Likewise, claim 3 is dependent on claim 1 and ***adds*** the requirement that the pharmacy be registered in the "computer readable storage medium" of claim 1. *Id.* The usage of "computer readable storage medium" in claims 1-3 of the '784 patent is inconsistent with Celgene's proposed construction. If the term "computer readable storage medium" required a single, centralized database in which all prescriber, pharmacy and patient registration information was stored, claim 1—through use of the term "computer readable storage medium" itself—would already require that all prescriber and pharmacy registration information be stored in a "computer readable storage medium," and dependent claims 2 and 3 would not further limit claim 1 and thus be improper. Claims 1-3 of the '977 patent are almost identical to claims 1-3 of the '784 and illustrate the same point. ECF No. 26-2, Hetero Answer Ex. B, '977 patent at claims. A requirement added by a dependent claim should not be read into the independent claim from which it depends. *See GE Lighting Sols., LLC v. Agilight, Inc.*, 750 F.3d 1304, 1310 (Fed. Cir. 2014). Accordingly, Celgene's proposed construction—which makes that precise error—should be rejected.

2. Prescription Approval Code

Claim Term	Celgene's Proposal	Defendants' Proposal
"prescription approval code" '720 patent claims 1-21, 23-32; '977 patent claims 1-23, 25-34; '784 patent claims 1-23, 25-34; '886 patent claims 1-7; '531 patent claims 1-40	a code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable	code representing consent to fill a prescription

The specification of the REMS patents describes a procedure for avoiding distribution of a drug to patients who might suffer adverse side effects if they receive the drug by (1) collecting information from the patient relating to whether the patient is likely to suffer the adverse side effect if the patient receives the drug, (2) assigning the patient to a "risk group" based on that collected information, (3) determining whether the risk that the patient suffers the adverse side effect is acceptable based on the collected information and risk-group assignment, and (4) generating a "prescription approval code" to be retrieved or received by the pharmacy if the risk is acceptable. Defendants contend that the term "prescription approval code" should be construed to mean a "code representing consent to fulfill a prescription," while Celgene contends that the term means "a code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable." As explained below, the evidence demonstrates that Defendants' proposed construction should be adopted.

First, the specification indicates that a "prescription approval code" is "preferably" not provided unless certain information—the prescriber, the pharmacy, the patient, the patient's risk group assignment and the patient's informed consent—is registered in the computer readable storage medium. ECF No. 26-1, Hetero Answer Ex. A, '720 patent 13:45-49. By use of the term "preferably," the specification implicitly indicates that a prescription approval may be provided even if this information—including the risk group assignment—is not registered in the computer readable storage medium. Moreover, the specification does not mention an "affirmative risk assessment" as the kind of information that is "preferably" registered in the computer storage medium before a prescription approval code is provided. This strongly suggests that an "affirmative risk assessment" is not required before a "prescription approval code" is provided.

The specification also indicates that, in certain circumstances, generation of the prescription approval code "may further require" the registration of additional information—including periodic surveys and the results of diagnostic tests—in the computer readable storage medium. *Id*. at 13:49-54, 14:67-15:3. But again, through use of the words "may further require," the specification indicates that a prescription approval code may be provided without the registration of this additional information in the computer readable storage medium. And more importantly, the specification does not even mention an "affirmative risk assessment" as the type of information that ***may*** be required before a prescription approval code is provided. Notably, no portions of the specification indicate that any particular information—and certainly not an affirmative risk assessment—***must*** be registered in the computer readable storage medium before a prescription approval code is provided.

Other language in the claims also supports the REMS Defendants' position. Specifically, many claims contain language explicitly stating that a prescription approval code is provided after an affirmative risk assessment has been made. For example, the final step of claim 1 of the '720 patent reads: "upon a determination that said risk is acceptable, generating a prescription approval code to be retrieved by said pharmacy before said prescription is filled." *Id*. at claim 1. Similarly, the final step of claim 1 of the '977 patent reads: "upon a determination that the risk is acceptable, generating the prescription approval code to be retrieved by the pharmacy before the prescription is filled." ECF No. 26-2, Hetero Answer Ex. B, '977 patent at claim 1. Other independent asserted claims – claim 28 of the '720 patent, and claim 1 of the '784 patent – contain similar language indicating that a prescription approval code is generated after an affirmative risk group assessment has been made. ECF No. 26-1, Hetero Answer Ex. A, '720 patent at claim 28; *id*. at Ex. C, '784 patent at claim 1. This language would be superfluous under Celgene's proposed construction of

"prescription approval code," which defines that term as inherently requiring that an affirmative risk group assessment has been made. Thus, Celgene's proposed construction violates the well-established rule that "claims are interpreted with an eye toward giving effect to all terms in the claim." *See Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012) (quoting *Bicon*, 441 F.3d at 950).

This case is very much like *Digital-Vending*, where the claim term to be construed was "registration server." Some of the claims further required that the claimed "registration server" be "free of content managed by the architecture." The district court construed term "registration server" to require a server that was "free of content managed by the architecture." The Federal Circuit reversed, stating as follows:

> If "registration server" were construed to inherently contain the "free of content managed by the architecture" characteristic, the additional "each registration server being further characterized in that it is free of content managed by the architecture" language in many of the asserted claims would be superfluous. . . In this case, the reference in some claims to a "registration server being further characterized in that it is free of content managed by the architecture" strongly implies that the term "registration server," standing alone, does not inherently mean a server that is free of managed content.

Id. at 1274-75. Here, if "prescription approval code" was interpreted to inherently require that an affirmative risk assessment had been made, then the additional language in many of the asserted claims requiring that the "prescription approval code" is generated after an affirmative risk assessment has been made would be superfluous. As in *Digital-Vending*, this strongly suggests that the term "prescription approval code" does not have the inherent characteristic of indicating that an affirmative risk assessment has been made.

Extrinsic evidence also supports the REMS Defendants' proposed construction. In *Celgene v. Natco*, Celgene itself proposed that the term "approval code" in the claims of the REMS patents should be interpreted to mean "symbol(s) representing consent to fill a prescription." *Celgene v. Natco*, D.I. 81, July 18, 2011 JCCS Ex. A at 1. Celgene even argued for this

construction in two briefs submitted to this Court. *Id*. at D.I. 86, Celgene Opening Claim Construction Br. at 14-16; *id*. at D.I. 111, Celgene's Responsive Claim Construction Br. at 8-9. Defendants' proposed construction of "prescription approval code" in this case—"code representing consent to fill a prescription"—simply replaces the word "symbol(s)" in Celgene's proposed construction from the *Celgene v. Natco* case with the word "code." This should be acceptable to Celgene since it has included "code" in its proposed construction in this case. Celgene can hardly argue that Defendants' proposed construction is unreasonable.

The one piece of evidence that supports Celgene's proposed construction is that, in an IPR proceeding involving the '720 patent, the PTAB adopted Celgene's proposed construction. But the PTAB's decision was largely based on a single, unexplained admission from the challenger's expert at a deposition, rather than on the intrinsic evidence. Murray Decl. Ex. G, FWD in IPR2015-01096 at 14-15. Defendants were not parties to that IPR proceeding and will not have an opportunity to examine that expert. Moreover, the PTAB held that all but one of the claims of the '720 patent was unpatentable due to obviousness, and thus the PTAB's narrower construction of "prescription approval code" was not necessary to its decision (*i.e.*, it would have held the claims unpatentable even if it had adopted the challenger's broader construction). In these circumstances, it would be unfair to give the PTAB's decision substantial weight.

One final piece of evidence merits discussion here. In the IPR proceeding, Celgene relied heavily on the following statement in the prosecution history of the '720 patent to support its position, although the PTAB did not appear to rely on that statement in reaching its decision:

> Claim 1 further requires an assessment, based upon the risk group assignment and information collected from the patient, as to whether the risk of the side effect occurring is acceptable. Upon a determination that the risk is acceptable, *and only upon such a determination*, a prescription approval code is generated, which must be retrieved by the pharmacy before the prescription may be filled. Thus, the prescription approval code is not merely a number that is associated with the prescription, but represents the fact that a

> determination has been made that the risk of the side effect occurring is acceptable, and that approval – an affirmative decision – has been made for the prescription to be filled.

Murray Decl. Ex. H, '720 PH, June 25, 2001 Amendment at 3-4 (emphasis in original). Celgene tries to twist this statement into a definition of "prescription approval code." But what the statement is really saying is that claim 1 ***as a whole*** requires a prescription approval code that represents the fact that an affirmative risk assessment has been made, and not that the term "prescription approval code" itself inherently includes such a requirement. The REMS Defendants do not dispute that claim 1 requires a prescription approval code that represents the fact that an affirmative risk group assessment has been made. But the language that imposes that requirement is not the term "prescription approval code" itself, but rather the words in the claim surrounding that term—namely, "upon a determination that said risk is acceptable, generating a prescription approval code to be retrieved by said pharmacy before said prescription is filled."

3. The "Generator" Term

Claim Term	Celgene's Proposal	Defendants' Proposal
"a generator configured to generate a prescription approval code" '531 patent claims 1-20	"prescription approval code" means "a code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable" No construction necessary for remainder of proposed language	Indefinite

Under 35 U.S.C. § 112, ¶ 6 (pre-AIA),[16] a claim element may be expressed as a means for performing a function recited in the claim. Such elements are referred to as "means-plus-function" limitations. Such a limitation covers the structure described in the specification for performing the recited function and its equivalents, rather than all structures that could perform that function. To be considered such a limitation, the term need not use the word "means." *Williamson*, 792 F.3d at 1348-49 (failure to use the word "means" creates a rebuttable presumption that 35 U.S.C. § 112, ¶ 6 does not apply, but it is not a strong presumption).

Claim 1 of the '531 patent recites "a generator configured to generate a prescription approval code." Defendants contend this term is a "means-plus-function" claim term but that it is indefinite because the specification does not "clearly link or associate" any structure with the recited function. Celgene contends that the term is not a means-plus-function limitation, and that it is not indefinite.[17]

If a claim term does not have a sufficiently definite meaning as the name for a structure but merely recites a function to be performed, then the term is a means-plus-function limitation. *Adv. Ground Info. Sys., Inc. v. Life360, Inc.*, 830 F.3d 1341, 1347-48 (Fed. Cir. 2016) (term "symbol generator" subject to § 112, ¶ 6 because the term is not used to designate structure). The term "generator configured to generate a prescription approval code" does not have a sufficiently definite meaning as the name for a structure ("generator" is not used in the specification), but

[16] In 2011, Congress passed the America Invents Act ("AIA"), Pub.L. No. 112-29, which took effect on September 16, 2012, and which amended 35 U.S.C. § 112 and renamed its subsections, previously named paragraphs 1-6, as paragraphs (a)-(f). *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1343 n.2 (Fed. Cir. 2015). Because the applications that issued into the REMS patents were filed before the AIA's effective date, the pre-AIA version of § 112 applies

[17] Celgene's proposed construction does not reveal its position on whether the term is a means-plus-function limitation. However, in its Response to Defendants' Invalidity Contentions on the REMS patents, Celgene stated its position. *See* Murray Decl. Ex. I, Celgene's Response to Defendants' Invalidity Contentions on the REMS patents at 174-75.

rather is simply another way of saying "means for generating." Accordingly, the term is a means-plus-function limitation subject to § 112, ¶ 6.

Where a claim term is subject to 35 U.S.C. § 112, ¶ 6, but the specification fails to "clearly link or associate" structure described in the specification with the recited function, the claim is invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2 (pre-AIA). *See Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003). Here, there is no structure described in the specification of the '531 patent that is clearly linked or associated with the recited function of generating a prescription approval code. The only references to generating a prescription approval code in the specification identify no structure for doing so. ECF No. 26-5, Hetero Answer Ex. E, '531 patent 13:41-53, 14:63-67, 16:11-22. Although the specification indicates that a prescription approval code is ***retrieved*** from a computer readable storage medium, it does not indicate that that medium ***generates*** the prescription approval code. The PTO stated as much during prosecution of an application in the chain leading to the '531 patent. Murray Decl. Ex. J, App. 11/437,551 PH, August 12, 2010 Office Action at 3 ("[t]he written description fails to disclose a computer readable medium "generating a prescription approval code.") and November 12, 2010 Office Action at 5. Accordingly, claim 1 of the '531 patent and the claims dependent therefrom (claims 2-20) are invalid for indefiniteness.[18]

V. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court adopt their constructions of the disputed terms.

[18] Claim terms may be held invalid for indefiniteness on this basis during the claim construction proceedings. *See Jazz Pharm., Inc. v. Amneal Pharm., LLC*, No. 13-0391 (ES) (JAD), 2017 WL 5128748, *4-8 (D.N.J. Nov. 6, 2017).

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CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of November, 2018, I caused the foregoing DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF to be filed via the Court's CM/ECF system and to be served upon all counsel of record by CM/ECF and electronic mail.

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